

DEC 16 2003

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## FACSIMILE TRANSMISSION

**from:** Diana L. Bush, Ph.D., Esq. **facsimile:** (858) 720-2555 **telephone:** (858) 720-2885 **Initials:** DLB4

**client name:** Metabasis Therapeutics, Inc. **client matter number:** 45198.00013.RCE

**date:** December 16, 2003 **pages (with cover):** 56

**to:** Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**company/office:** USPTO  
Group Art Unit  
1624

**facsimile:** 703 872-9306

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## comments:

U. S. Patent Application No. 09/518,501  
NOVEL PHOSPHORUS-CONTAINING PRODRUGS  
Applicant: Erion et al.  
Filing Date: March 3, 2000  
Our Ref: 45198.00013.RCE

Attached hereto are the following documents for filing in the above patent application:

1. Fee Transmittal Sheet
2. Petition for Extension of Time & Response
3. Interview Summary
4. Executed Declaration of John C. Chabala Pursuant to 37 C.F.R. § 1.132

CERTIFICATE OF TRANSMISSION  
(37 C.F.R. §1.8)

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# FEE TRANSMITTAL for FY 2003

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT (\$750.00)

## Complete If Known

Application Number 09/518,501  
 Filing Date December 16, 2003  
 First Named Inventor Erion et al.  
 Examiner Name McKenzie, T.  
 Group Art Unit 1624  
 Attorney Docket No. 45198.00013.RCE

## METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to:

Deposit  
Account  
Number

50-2613

Deposit  
Account  
Name

- ☒ Charge Any Additional Fee Required  
Under 37 CFR 1.16 and 1.17  
☐ Applicant claims small entity status. See  
37 CFR 1.27

Charge fee(s)

2. ☒ Indicated below:

## FEE CALCULATION

## 1. BASIC FILING FEE

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	620	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	180	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$ 0)

## 2. EXTRA CLAIM FEES

Total Claims 1  
 Independent Claims 1  
 Multiple Dependent

Extra Claims 20<sup>\*\*</sup> = 0  
 3<sup>\*\*</sup> = 0

Fee from below = 0  
 Fee Paid = 0

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
1202	18	2202	9	Claims in excess of 20	
1201	84	2201	42	Independent claims in excess of 3	
1203	280	2203	140	Multiple dependent claim, if not paid	
1204	84	2204	42	** Reissue Independent claims over original patent	
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent	
SUBTOTAL (2)					(\$ 0)

<sup>\*\*</sup>or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

## 3. ADDITIONAL FEES

Large Fee Code	Entity Fee (\$)	Small Fee Code	Entity Fee (\$)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for ex parte reexamination	
112	920 <sup>*</sup>	112	920 <sup>*</sup>	Requesting publication of SIR prior to Examiner action	
113	1,840 <sup>*</sup>	113	1,840 <sup>*</sup>	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	390	216	195	Extension for reply within second month	
117	690	217	445	Extension for reply within third month	\$475.00
118	1,390	218	695	Extension for reply within fourth month	
128	1,890	228	945	Extension for reply within fifth month	
119	310	219	155	Notice of Appeal	
120	310	220	155	Filing a brief in support of an appeal	
121	270	221	135	Request for oral hearing	
138	1,510	138	1,510	Petition to Institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,240	241	620	Petition to revive - unintentional	
142	1,240	242	620	Utility issue fee (or reissue)	
143	440	243	220	Design issue fee	
144	600	244	300	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Processing fee under 37 CFR 1.17(q)	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
148	710	248	355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	710	249	355	For each additional invention to be examined (37 CFR § 1.129(b))	
179	710	279	355	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	

Other fee (specify)

<sup>\*</sup>Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 475.00)

## SUBMITTED BY

Complete (if applicable)

Name (Print/Type)

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Date

12/16/03

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45198.00013.RCE  
Patent**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Applicants: Erion *et al.*

Serial No.: 09/518,501

Filed: March 3, 2000

Title: NOVEL PHOSPHORUS-CONTAINING  
PRODRUGS

Group Art Unit: 1624

Examiner: McKenzie, T.

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**INTERVIEW SUMMARY**

On September 10, 2003, Examiner McKenzie and his supervisor Mukund Shah conducted an in-person interview with Applicants' attorney Jessica Wolff and Dr. Mark Erion with regard to Application No. 09/518,501. Also present telephonically were Applicants' attorney Diana Bush and Applicants' patent agent, Cynthia O'Donohue. Application No. 09/747,182 was also discussed.

In regard to this Application, the following topics were discussed:

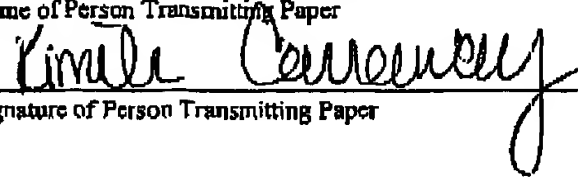
1. Examiner's indefiniteness, lack of written description, and non-enablement rejections based on the term "M is selected from the group that attached to  $\text{PO}_3^{2-}$ ,  $\text{P}_2\text{O}_6^{3-}$ ,  $\text{P}_3\text{O}_9^{4-}$  or  $\text{P}(\text{O})(\text{NHR}^6)\text{O}^-$  is a biologically active agent but is not an FBPase inhibitor" in claims 1-3, 7, 9-18, 20-46, 48-53, 150-157, 165-166, and 171-173.

Applicants described the technology of the invention, data, and how the invention is applied. The Examiners expressed concerns regarding PTO policy on functional language in light of the *University of Rochester Cox 2* inhibitor district court decision.

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45198.00013.RCE  
Patent

Applicants distinguished that case and emphasized the amount of data taught in the current application. Examiner McKenzie expressed that he has no doubt that there is allowable subject matter, but that it is more an issue of the breadth of the claims. Examiner Shah indicated that if the Applicants submitted evidence and arguments that the claims do meet the requirements of definiteness, written description, and enablement, he will further evaluate the functionality issue and ascertain if quality control would consider these claims as meeting the functional guidelines based on the evidence and arguments presented.

2. Examiner's indefiniteness, lack of written description, and non-enablement rejections for the term "prodrug" in claims 1-18, 20-46, 48-57, 150-157, and 165.

Applicants discussed that many issued patents use this language in the claims. Examiner Shah indicated that this language does meet the requirements for definiteness, written description, and enablement.

3. Examiner's indefiniteness rejection of claims 155-157 and 166 based on the term "oxidizing agent."

Examiner Shah indicated that this language does meet the requirement of definiteness.

Respectfully submitted,

Dated: 12/16/03

By:

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